

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)						February 2002				
BUDGET ACTIVITY 3 - Advanced technology development				PE NUMBER AND TITLE 0603105A - MILITARY HIV RESEARCH			PROJECT H29			
COST (In Thousands)				FY 2001 Actual	FY 2002 Estimate	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate
H29	MED PROTECT AGNST HIV			5661	5885	0	0	0	0	0
<p><u>A. Mission Description and Budget Item Justification:</u> This project supports the medical technology area of the Objective Force by conducting concept exploration of candidate vaccines to include safety and efficacy in model systems to prepare and conduct clinical studies. It funds Acquired Immune Deficiency Syndrome (AIDS) research to control the infection in military environments, protect the military blood supply, and protect military personnel from risks associated with infection. AIDS research is focused on the following areas: diagnosis, natural history, epidemiology, and vaccine development. Preclinical trials and phase 1, 2, and 3 clinical trials are performed as required for drug and vaccine licensure with US Food and Drug Administration. The cited work is consistent with the Army Science and Technology Master Plan (ASTMP), the Army Modernization Plan and Project Reliance. The program element contains no duplication with any effort within the Military Departments. Major contractor is the Henry M. Jackson Foundation, Rockville MD. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).</p> <p><u>FY 2001 Accomplishments:</u></p> <ul style="list-style-type: none">5661<ul style="list-style-type: none">- Conducted clinical studies of HIV drug resistance for the management of HIV infection in military service members and other military health-care beneficiaries.- Conducted phase 1 and 2 clinical trials of candidate vaccines and novel vaccine delivery systems to test their safety and their ability to produce an immune response.- Prepared for phase 1 study of a live virally-delivered candidate HIV vaccine in Uganda. <p>Total 5661</p> <p><u>FY 2002 Planned Program</u></p> <ul style="list-style-type: none">5885<ul style="list-style-type: none">- Define HIV virus and immune system factors that are associated with immunity.- Produce clinical-grade quantities of a candidate DNA vaccine against HIV serotype D and virally-vectored vaccines against HIV serotypes D and E, which are found outside the United States and therefore important in deployed military infections.- Conduct pre-clinical studies of candidate HIV vaccines in animal models to determine safety and efficacy for producing an immune response before studies are begun in humans.- Develop HIV vaccine cohorts for future field trials in Kenya and Tanzania.										

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BUDGET ACTIVITY

PE NUMBER AND TITLE

PROJECT

3 - Advanced technology development**0603105A - MILITARY HIV RESEARCH****H29****FY 2002 Planned Program (Continued)**

- Conduct a multi-center clinical study to investigate HIV drug resistance.
- Conduct a phase 1 study of a live virally delivered candidate HIV vaccine in Uganda.

Total 5885

FY 2003 Planned Program

Program transferred to the National Institutes of Health.

<u>B. Program Change Summary</u>	FY 2001	FY 2002	FY 2003
Previous President's Budget (FY2002 PB)	5834	5937	6073
Appropriated Value	5889	5937	0
Adjustments to Appropriated Value	0	0	0
a. Congressional General Reductions	0	-52	0
b. SBIR / STTR	-174	0	0
c. Omnibus or Other Above Threshold Adjustments	0	0	0
d. Below Threshold Reprogramming	0	0	0
e. Rescissions	-54	0	0
Adjustments to Budget Years Since FY2002 PB	0	0	-6073
Current Budget Submit (FY 2003 PB)	5661	5885	0

Change Summary Explanation: Funding: FY 2003 - Program responsibility for management and oversight of HIV R&D efforts have been transferred to the National Institutes of Health (NIH).